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October 10, 2024

By ECF
Hon. Douglas E. Arpert, U.S.M.J. (Ret.)
Three Gateway Center
100 Mulberry Street
15th Floor
Newark, New Jersey 07102

Re: **United States ex rel. Silbersher v. Janssen Biotech Inc., et al., Civil Action No. 19-12107 (MEF-SDA)**

Dear Judge Arpert:

Defendants respectfully submit this letter to briefly address new factual issues Relator raises in his 18-page opposition ("Relator's Opposition") (ECF No. 376) to Defendants' letter asking the Court to strike (i) Relator's damages expert's second amended report; and (ii) all of Relator's experts' blanket reservations of rights to testify about "any subject matter within [their] expertise" at a later time. (ECF No. 372).

Relator's Opposition acknowledges that Relator was well aware of the significant deficiencies in his expert reports prior to the deadline for serving them. Yet rather than ask the Court for an extension, Relator knowingly served deficient reports, intending to amend long after the deadline. In seeking to excuse these deficiencies, Relator misrepresents the record in at least two significant ways.

First, Relator alleges that his damages expert, Dr. Hal Singer, was unable to serve a timely, complete report because Defendants "wrongfully refused" to provide a corporate representative for deposition on Relator's 30(b)(6) Topic 18, including the "sale of any Authorized Generic of Zytiga" by Defendants' affiliate, Patriot Pharmaceuticals, LLC. Relator's Opposition at 11. That is false.

Defendants produced a corporate representative for deposition on the "sale of any Authorized Generic of Zytiga": Ken Nelson, the Director of Government Contracts for Johnson & Johnson Healthcare Systems. Relator deposed Mr. Nelson on May 30, 2024—months before Relator's experts reports were due. The parties agreed that Mr. Nelson's testimony on Topic 18 would include "sales of Authorized Generic Zytiga." *See* Ex. A, J&J Responses & Objections to Relator's 30(b)(6) Deposition Notice at 23; *see* Ex. B., May 8, 2024 Email from B. Morrissey. At

the deposition, Relator's counsel asked, and Mr. Nelson confirmed, that he was prepared to testify on this topic. Ex. C, Nelson Dep. Tr. 36:13–16. Relator questioned Mr. Nelson for more than five hours. Yet Relator asked Mr. Nelson *no questions* about any actual authorized generic Zytiga sales. In particular, he asked *no questions* regarding the "NDC code" for authorized generic Zytiga that Relator now claims is essential to his damages expert's analysis.[1] In sum, Defendants provided the 30(b)(6) witness Relator requested. Relator's failure to ask questions on this topic in the deposition is entirely his own, and is no justification for his deficient expert report.

Second, Relator asserts that Defendants should have included authorized generic sales data in their document productions, and that he only learned of the absence of this data when "completing" Singer's report. Again, this is an issue of Relator's own making. Fact discovery was open for nearly three years. Defendants produced multiple years of transactional data for Zytiga more than 15 months ago, in June 2023. Relator did *not* request the production of sales data for authorized generic Zytiga,[2] and Defendants twice expressly advised Relator in writing that the that their document productions did *not* include sales data for the authorized generic: "As stated in Defendants' April 25, 2022 Responses and Objections, this production includes data for Zytiga and *not* generic Zytiga." Ex. E, June 9, 2023 Letter at 1 n.2 (emphasis added).

Relator's failure to ask for authorized generic sales data struck Defendants as unsurprising because his Complaint focuses solely on *branded* Zytiga—it makes no allegations regarding the authorized generic. In any event, Relator raised no concerns about this issue and took no steps to pursue it for the last 15 months, despite obtaining two extensions of the fact discovery deadline. He therefore cannot plausibly cite this as an excuse for his failure to serve a complete expert report on the deadline negotiated by the parties and approved by the Court.

Finally, as to Relator's experts' blanket reservations of rights to offer additional, undisclosed opinion testimony down the road, Relator makes no attempt to defend them on the merits. Rather, he first resorts to the fallacy of "they did it too." It does appear that one of the ten expert reports filed on behalf of Defendants in the ANDA litigation in 2017 included a similar reservation. That was wrong then, as Relator is now. Second, Relator concedes the baselessness of his reservations by restricting them to opinions "permitted by the rules." Although Defendants appreciate this limitation, that is not what the reports say, and Relator's conduct to date renders this cold comfort. If Relator's forthcoming as-of-yet undisclosed opinions are permitted by the

[1] Relator's claim that deposition testimony was necessary to obtain the NDC code is specious in any event. NDC information for Patriot's abiraterone acetate product is readily available in the public domain, as shown by a simple Google search for "Patriot," "abiraterone," and "NDC."

[2] Relator requested the production of sales data only for "Zytiga," (which he defined to include only Defendants' "trademark[ed]" brand name product) and "Generic Zytiga" (which he defined mean generic products sold by third parties—*i.e.*, generics that sought FDA approval based on an abbreviated new drug application ("ANDA") "for which Zytiga is the reference listed drug." *See* Ex. D, Relator's Am. Requests for Production (Mar. 25, 2022) at 3–4, 8 (Definitions Nos. 16, 26, 56); *id.* at 21 (Request No. 32). As defined by Relator, neither term encompasses Defendants' "Authorized Generic," which did not require FDA approval pursuant to an ANDA. Indeed, Relator himself defined the "Authorized Generic" as a separate term, and he did not request sales data for that term. *Id.* at 3, 21.

rules, he should have no problem disclosing them to Defendants and seeking leave of the Court in advance of serving any new, revised, or supplemental expert report. The Court should instruct Relator to follow that procedure.

For these reasons, and the reasons stated in Defendants' letter (ECF 372),[3] Defendants' request to strike the Second Amended Singer report, and the blanket reservations in Relator's other expert reports, should be granted.

Respectfully yours,

/s/ Jeffrey J. Greenbaum

Jeffrey J. Greenbaum

cc: Counsel of Record (via ECF and Email)

[3] Relator's claim that Defendants' letter was required to comply with L. Civ. R. 37.1(b)'s affidavit requirement for formal discovery motions is without foundation. The Rule explicitly states that a "letter" that "shall precede any formal motion." L. Civ. R. 37.1(a). Defendants submitted such a letter here. This is consistent with the parties' past practice in discovery disputes before the Special Master and the Magistrate Judge.